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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,897	01/17/2001	John J. Harrington	0221-00030(C)	3522
7590 01/21/2004			EXAMINER	
SHANKS & HERBERT TransPotomac Plaza 1033 N. Fairfax St., Suite 306 Alexandria, VA 22314			SHUKLA, RAM R	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,897

Applicant(s)

HARRINGTON ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 78-80 and 83-97 is/are pending in the application.
- 4a) Of the above claim(s) 78-80, 83-91 and 95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 92-94, 96 and 97 is/are rejected.
- 7) ☒ Claim(s) 81 and 82 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election with traverse of the invention of group III, claims 92-94 and 96-97 in Paper filed 10-9-2003 is acknowledged. The traversal is on the ground(s) that (i) the burden of search will not be increased if the groups are examined together; (ii) applicants' discussion with Jim Housel; (iii) and that the inventions are not related as a product and method of using the method. This is not found persuasive because restriction is required not only when search is burden but also because of the burden of examination.

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. (MPEP 803).

Regarding, applicants discussion with Jim Housel, examiner is not aware of what was discussed between applicants and Jim Housel, therefore, this can not be a reason for withdrawing restriction. Additionally, examiner talked to his supervisor regarding this issue and she agreed with the examiner.

Applicants' arguments that the inventions are not related as product and method of use are not persuasive because the invention of group III is a cell while the inventions of groups I and II are a methods and use the cells of group III.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 78-80, 83-91 and 95 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed 10-9-2003.

3. As noted in the previous office action of 9-9-2003, claims 81 and 82 are objected to because they are dependent on cancelled claims and therefore, have not been considered. For a response to this office action to be complete, applicants are required to cancel these claims.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 92-94 and 96-97 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a purified cell as claimed wherein the cell is a eukaryotic cell, does not reasonably provide enablement for any cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make and use the claimed invention, if not, whether an artisan would have required undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue" (In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). Furthermore, USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

The invention as claimed encompasses any cell including a prokaryotic cell. The specification as filed does not teach how to make a prokaryotic cell in which an artisan could introduce the vector comprising a genetically engineered vector that comprised a splice donor site and the splice donor site splices to a splice acceptor site of an endogenous gene in the genome of the cell. At the time of the invention an artisan would not have known how to make a prokaryotic cell since splice acceptor site was known to be present in the genome of prokaryotic cells and due to the absence of splicing machinery in a eukaryotic cell, splicing could not occur. The presence of introns is a characteristic of nuclear RNA and interrupted genes in higher eukaryotes and for making a protein from a gene which comprises splice donor sites, splice acceptor sites and other sequence requirements for splicing such as branch point, poly U tract etc. are required (see mechanism of splicing, chapter 30, pages 595-599, in Genes IV. B. Lewin, Oxford Univ. Press, 1990). Since these requirements could not be met in a prokaryotic cell, an artisan could not make a prokaryotic cell encompassed by the claimed invention.

An artisan would have required undue experiment to make the claimed cell commensurate with the full scope of the claims because splicing system was not known to exist in the prokaryotic cells for expressing proteins and neither the art nor the specification provides any guidance to make the cell. Therefore, limiting the scope of the claimed invention to a purified eukaryotic cell is proper.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 92-94 and 96-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 92 is vague and indefinite because there is no antecedent basis for the term "genetic vector" in line 2.

Claim 92 is also vague because there is not antecedent basis for the term "the vector" in line 7. It is not clear whether "the vector" refers to "a genetically engineered vector " or to "the genetic vector".

Claims 92-94 and 96-97 are vague and indefinite because the metes and bounds of the term "being linked effectively" are not clear.

Claims 92-94 and 96-97 are also vague and indefinite because it is not clear as to how the vector is comprised in the genome of a cell. The metes and bounds of the term "said cell comprising in its genome" are not clear.

Claim 92-94 and 96-97 are also vague and indefinite because it is not clear as to what is meant by "upstream region" and what is encompassed by the claimed invention. The metes and bounds of the term are not clear.

8. No claim is allowed.

9. Examiner's Note:

It is noted that while the art of record teach activation of endogenous oncogenes due to the integration of retroviruses and cells in which the expression of an oncogene is enhanced due to retroviral integration (eg. Baumbach et al. Journal of Virology 62 :3151-3155, 1988, see the abstract; Varmus Science 240:1427-1435, 1988, see the abstract; Bartholomew et al. Oncogene 4:529-534, 1989), these arts do not teach a cell encompassed by the claimed invention as recited.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this

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application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

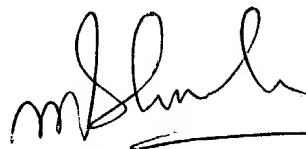
Please note that effective January 13, the offices for Examiner Shukla, SPE Reynolds and LIE William Phillips will move to the new USPTO location in Alexandria, VA and their phone numbers will change. The new phone numbers will be as follows:

Ram Shukla: **(571) 272-0735**

Deborah Reynolds: **(571) 272-0734**

William Phillips: **(571) 272-0548**

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632


RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER